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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,945	01/26/2004	David Tsai	03-10-2151	8274
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STEELE, AMBER D				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/764,945

**Applicant(s)**

TSAI, DAVID

**Examiner**

Amber D. Steele

**Art Unit**

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on December 18, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-13, 15, and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/19/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of the Claims***

1. Claims 1-17 are currently pending.  
Claims 11, 14, and 16 are currently under consideration.

***Election/Restrictions***

2. Applicant's election without traverse of Group IV (claims 11, 14, and 16) in the reply filed on December 18, 2007 is acknowledged.
3. Claims 1-10, 12-13, 15, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 18, 2007.

***Priority***

4. The present applications claims status as a CIP of 10/267,706 (filed October 8, 2002; now U.S. Patent 7,238,662) which is a CIP of 10/145,682 (filed May 14, 2002; now U.S. Patent 6,720,311) which is a CIP of 09/902,208 (filed July 9, 2001; now U.S. Patent 6,737,402) which is a CIP of 09/414,136 (filed October 7, 1999; now U.S. Patent. 6,258,779) which is a CIP of 09/149,878 (filed September 8, 1998; now U.S. Patent 5,994,298) which is a CIP of 08/993,432 (filed December 18, 1997).
5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 10/267,706; 10/145,682; 09/902,208; 09/414,136; 09/149,878; and 08/993,432, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the prior-filed applications disclose alpha 1-acid glycoprotein or methods of preparing zinc charged alpha 1-acid glycoprotein. Therefore, the present priority date is the filing date of the present application (i.e. January 26, 2004).

#### ***Information Disclosure Statement***

6. The information disclosure statement (IDS) submitted on October 19, 2007 is being considered by the examiner.

#### ***Specification***

7. The disclosure is objected to because of the following informalities: the first line of the specification should be amended to indicate that U.S. application 10/267,706 issued as U.S. Patent 7,238,662 on July 3, 2007; U.S. application 10/145,682 issued as U.S. Patent 6,720,311 on April 13, 2004; and U.S. application 09/902,208 issued as U.S. Patent 6,737,402 on May 18, 2004.

Appropriate correction is required.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

9. Claim 11 is objected to because of the following informalities: line 2 reads "for treatment on cancer cells", "for treatment of cancer cells" is suggested and line 2 of method step (c) reads "Zinc Acetate", the lower case version of the reagent is suggested. Appropriate correction is required.

***Invention as Claimed***

10. A process for preparing zinc charged alpha 1-acid glycoprotein comprising: (a) incubating said alpha 1-acid glycoprotein in solution with a chelating agents, (b) isolating naked alpha 1-acid glycoprotein from step (a), (c) incubating said naked alpha 1-acid glycoprotein in solution with zinc acetate, (d) isolating zinc charged alpha 1-acid glycoprotein from the solution in step (c), and variations thereof.

Please note: the (a) suitable for treatment of cancer cells (claim 11) and (b) apoptotic activity (claims 14 and 16) claim language is considered intended use language for the final product produced by the presently claimed method and is not provided patentable weight. In addition, any method reciting all of the method steps and reagents as presently claimed would produce a product with the same inherent properties as the final product as claimed. Please refer to MPEP § 2106, section C; § 2111.02, section II; and § 2112.02.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Tsai et al. U.S. Patent 6,720,311 (effective filing date of December 18, 1997); Lebreton et al. J. Clin. Invest. 64: 1118-1129, 1979; and Aebersold et al. U.S. Patent 7,183,118 (effective filing date of May 9, 2003).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

For present claim 11, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent, (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc acetate, and (d) isolating zinc charged fetuin (please refer to the entire specification particularly the abstract; column 13, lines 27-47; column 15, lines 46-67; column 16; column 17, lines 1-57).

For present claim 14, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent, (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc, (d) isolating zinc charged fetuin, (e) drying the zinc charged fetuin, and (f) isolating peptide fragments of zinc charged fetuin (please refer to the entire specification particularly the abstract; column 13, lines 27-47; column 15, lines 46-67; column 16; column 17, lines 1-57).

For present claim 16, Tsai teaches methods for preparing zinc charged serum proteins including fetuin (i.e. alpha 2-HS glycoprotein) which is a member of the acute-phase and seromucoid class of proteins comprising (a) incubating bovine serum albumin or fetuin with a chelating agent, (b) isolating “naked” fetuin, (c) incubating “naked” fetuin with zinc acetate, (d) isolating zinc charged fetuin, (e) incubating the zinc charged fetuin with protease (i.e. proteinase K), and (f) isolating peptide fragments of zinc charged fetuin (please refer to the entire specification particularly the abstract; column 13, lines 27-47; column 15, lines 46-67; column 16; column 17, lines 1-57).

However, Tsai does not teach zinc supercharging of other seromucoid proteins.

For present claims 11, 14, and 16, Lebreton et al. teach that both fetuin (i.e. alpha 2 HS glycoprotein) and orosomucoid (i.e. alpha 1-acid glycoprotein) are acute phase serum proteins (i.e. seromucoid class) and teach methods of isolating the proteins from human serum via zinc affinity chromatography and EDTA elution (please refer to the entire reference particularly the abstract; paragraph spanning the left and right columns of page 1119; page 1121, left column; page 1123, right column).

However, neither Tsai nor Lebreton et al. teach papain digestion of proteins.

For present claim 16, Aebersold et al. teach protease digestion of various glycoproteins including alpha 1-acid glycoprotein and alpha 2-HS glycoprotein (i.e. fetuin) with papain (please refer to the entire specification particularly Figures 1 and 16; column 11, lines 56-67; Tables 4-5 and 7).

All the claimed elements (e.g. acute phase seromucoid protein alpha 1-acid glycoprotein, zinc, chelators, papain) were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods (e.g. utilizing chelators, utilizing proteases including papain, ability of proteins to bind metals including zinc) with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Alternatively, the claim would have been obvious because the substitution of one known element (i.e. fetuin and proteinase K) for another (i.e. alpha 1-acid glycoprotein and papain) would have yielded predictable results (e.g. papain will cleave cysteine residues of proteins, a positive metal can bind negatively charged protein residues, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR Int'l Co. V. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).



***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Patent Examiner, Art Unit 1639

February 26, 2008